

REMARKS

Amendments to the Claims

With this amendment, claims 1-15 and 17-25 are pending. Claims 1-12 and 16-19 have been amended. Claims 13-15 and 20-25 have been withdrawn as drawn to a non-elected invention. Claim 16 has been canceled without prejudice or disclaimer.

Claims 2-12 and 19 have been amended merely to correct matters of formality. Claims 17 and 18 have been amended to correct their dependencies and to provide proper antecedent basis. Claim 1 has been amended to recite “[a] method of identifying a candidate retinoblastoma (RB) pathway modulating agent, said method comprising the steps of: (a) providing a first assay system comprising a Chaperonin containing T-complex 1 subunit 6A (CCT6) polypeptide or nucleic acid; (b) contacting the first assay system with a test agent; (c) determining the expression or activity of the CCT6 polypeptide or nucleic acid in the first assay system in the presence or absence of the test agent of step (b), wherein a change in the expression or activity of CCT6 polypeptide or nucleic acid in the presence of said test agent identifies the test agent as a candidate RB pathway modulating agent; (d) confirming that the test agent of (b) is a candidate RB pathway modulating agent by providing a second assay system comprising a CCT6 polypeptide or nucleic acid, wherein the second assay system is able to measure the RB pathway; (e) contacting the second assay system with the test agent of step (b); and (f) measuring the RB pathway in the second assay system in the presence or absence of the test agent of step (b), wherein a change in the RB pathway in the presence of said test agent confirms the test agent as a candidate RB pathway modulating agent. Support for the amendments to claim 1 is found throughout the specification, for example, at pages 3, 4, 13, 20, 29 and 36-39.

35 USC § 102(b) Rejections

Claims 1-6 and 8 have been rejected under 35 USC 102(b), as allegedly being anticipated by Kornblau et al. (Cancer Research, 1994, 54:242-246) as evidenced by Li, J. Biol. Chem., 269: 186:16-18622. Applicants respectfully traverse the rejections.

The Office alleges that Kornblau et al. anticipates claims 1-6 and 8 because it allegedly teaches a method of identifying an RB modulating agent using an assay system comprising a CCT6 polypeptide or nucleic acid. Specifically, the Office Action states that Kornblau et al. teaches contacting chronic leukemic lymphocytes (CLL) with PWM and PHA whereby a difference in RB expression is detected between the reference point (control) and the PWM and PHA treated cell. Li et al is cited as an evidentiary reference to show that the CLL taught by Kornblau et al expresses CCT6 and therefore meets the limitation of an assay system providing a CCT6 polypeptide or nucleic acid.

Under 35 U.S.C. § 102, a claim is anticipated only if each and every element as set forth in the claim is found in a single art reference. *Verdegaal Bros. v. Union Oil Co.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 10533 (Fed. Cir. 1987); *In re Recombinant DNA Technology Patent and Contract Litigation*, 30 USPQ2d 1881 (S.D. Ind.1993) (“A patent is anticipated only if all the elements and limitations of the claims are found within a single, prior art reference. No difference may exist between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of invention.”); *Structural Rubber Products Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984) (All elements of the claimed invention must be contained in a single prior art disclosure and must be arranged in the prior art disclosure as in the claimed invention); M.P.E.P. § 2131. The identical invention must be described or shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); *Chester v. Miller*, 15 USPQ2d 1333 (Fed. Cir. 1990); M.P.E.P. § 2131.

Applicants submit that Kornblau et al. does not anticipate the present invention because it fails to teach each and every element as set forth in the claims. Claim 1, as amended, recites a method for identifying a candidate RB pathway modulating agent, comprising (a) providing a first assay system comprising a CCT6 polypeptide or nucleic

acid; (b) contacting the first assay system with a test agent; (c) determining the expression or activity of the CCT6 polypeptide or nucleic acid in the first assay system in the presence or absence of the test agent of step (b), wherein a change in the expression or activity of CCT6 polypeptide or nucleic acid in the presence of said test agent identifies the test agent as a candidate RB pathway modulating agent; (d) confirming that the test agent of (b) is a candidate RB pathway modulating agent by providing a second assay system comprising a CCT6 polypeptide or nucleic acid, wherein the second assay system is able to measure the RB pathway; (e) contacting the second assay system with the test agent of step (b); and (f) measuring the RB pathway in the second assay system in the presence or absence of the test agent of step (b), wherein a change in the RB pathway in the presence of said test agent confirms the test agent as a candidate RB pathway modulating agent.

Among other things, claim 1 requires determining the expression or activity of the CCT6 polypeptide or nucleic acid in the first assay system in the presence or absence of the test agent (step (c)). Kornblau et al. reports that RB expression can be altered in CLL cells and specifically measures the level of RB expression in the presence of PWM and PHA. However, Kornblau et al. does not recognize a connection between CCT6 and the RB pathway and, in fact, fails to mention CCT6 altogether. Thus, Kornblau et al. fails to teach a method for identifying a candidate RB pathway modulating agent, wherein the expression or activity of a CCT6 polypeptide or nucleic acid is determined in the presence or absence of a test agent. Furthermore, Kornblau fails to teach a method for identifying a candidate RB pathway modulating agent in which a first assay is used to determine a change in the expression or activity of a CCT6 polypeptide or nucleic acid in the presence of a test agent and a second assay is used to determine a change in the RB pathway in the presence of said test agent. Thus, Kornblau et al fails to teach each and every step of the claimed invention.

For the reasons set forth above, Kornblau et al does not anticipate the claimed invention. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejections based on Kornblau et al.

Claims 1-5, 7 and 8 have been rejected under 35 USC 102(b), as allegedly being anticipated by Li, J. Biol. Chem., 269: 186:16-18622. Applicants respectfully traverse the rejections.

The Office alleges that Li et al teach a method of screening an antibody binding to Top20 using CLL lysate. However, similar to Kornblau et al, Li does not recognize the connection between CCT6 and the RB pathway and, in fact, does not mention RB or the RB pathway at all. Thus Li does not teach a method for identifying a candidate RB pathway modulating agent in which a first assay is used to determine a change in the expression or activity of a CCT6 polypeptide or nucleic acid in the presence of a test agent and a second assay is used to determine a change in the RB pathway in the presence of said test agent. Thus, Li et al fails to teach each and every step of the claimed invention.

For the reasons set forth above, Li et al does not anticipate the claimed invention. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejections based on Li et al.

Claims 1 and 8-10 have been rejected under 35 USC 102(b), as allegedly being anticipated by US 20030109465 (the '465 application). Applicants respectfully traverse the rejections.

The Office alleges that the '465 application teaches the use of an antisense oligonucleotide to block the expression of TGF-B in human cells. The Office further alleges that the human cells inherently have genomic CCT6 nucleic acid. Thus, the Office concludes that the '465 application teaches the claimed methods because it teaches providing a TGF-B antisense oligomer to human cells, which presumably have CCT6 nucleic acid. However, the '465 application relates to TGF-B blocking agents. It does not mention CCT6 or the RB pathway at all. Thus the '465 application does not teach a method for identifying a candidate RB pathway modulating agent in which a first assay is used to determine a change in the expression or activity of a CCT6 polypeptide or nucleic acid in the presence of a test agent and a second assay is used to determine a change in the RB pathway in the presence of said test agent. Thus, the '465 application fails to teach each and every step of the claimed invention.

For the reasons set forth above, the '465 application does not anticipate the claimed invention. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) rejections based on Li et al.

CONCLUSION

In view of the above remarks, the application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue.

Respectfully submitted,
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